A14300 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: July 19, 2010
UMDNS Terms:
- Stretchers, Mobile, Ambulance [16630]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Emergency/Outpatient Services
- EMS/Transport

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- U.K.

Stryker—Model 6100 M1 Ambulance Cots: Head End May Collapse, Potentially Causing User or Patient Injury

Product Identifier:
Model 6100 M1 Ambulance Cots *[Capital Equipment]*
Product No. 6100-XXX-XXX; Serial Nos.: 001239066 through 091139098

Manufacturer: Stryker Medical Div Stryker Corp [271227], 3800 E Centre Ave, Portage, MI 49002, United States

Problem:
In a July 2, 2010, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Stryker states that the head end slide tubes, bushings, and head end release rods of the above ambulance cots may break during use, potentially resulting in the collapse of the head end. The manufacturer has not confirmed the information provided in the source material.

Manufacturer/Regulatory Agency:	Designation:
Stryker	Reference No. RA 2010-079
MHRA	Reference No. 2010/006/029/081/009; may issue further advice

Action Needed:
Verify that you have received the July 2, 2010, Urgent Field Safety Notice letter and customer response form from Stryker. Identify any affected product in your inventory. The serial number is located at the center of the bottom rail at either the head end or the foot end. If product does not operate properly, remove it from service and contact your Stryker local distributor as soon as possible. Product that is not operating properly should be kept out of service until it can be repaired by a Stryker-authorized field service technician. Inform all relevant personnel at your facility of the information in the Urgent Field Safety Notice letter. Notify Stryker if you have further distributed affected product to other facilities. Inform Stryker of any adverse events associated with use of affected product. Regardless of whether you have affected product, complete the customer response form and return it to Stryker by fax at (01635) 262464 within the U.K. or using the information on the form outside the U.K. Upon receipt of the form, a Stryker representative will contact your facility to arrange for upgrade of all product regardless of whether it is currently operating correctly.

For Further Information:			
Geographic Location:	Contact:	Telephone No.:	Web Site:
U.K.	Stryker	(01635) 262402	Click here
Outside the U.K.	Stryker local representative		

Source:
- Great Britain. Medicines and Healthcare Products Regulatory Agency. Stretchers: ambulance trolley—Stryker Medical—Model 6100 M1 ambulance cot [online]. London: Department of Health; 2010 Jul 15 [cited 2010 Jul 15]. 1 p. (Field safety notice; reference no. 2010/006/029/081/009). Available from Internet: Click here.

Comment:
- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a

separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.

- This alert is based on information that may not be independently verified as to its accuracy, completeness, or causal relationship to the product or its supplier.

- The manufacturer has not confirmed the geographic distribution of affected product. ECRI Institute recommends that you check your inventory for this product regardless of where you are located.

Verification History: Alert Confirmed by Non-U.S. Regulatory Agency [7/16/2010 11:54:50 AM]